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Rollins 183
942666 12/17/86
TAI-SHUN LIN, ET AL.

USE OF 3', DEOXYTHYMIDIN-2'-ENE (3'DEOXY-2',3'-DIDEHYDROTHYMIDINE) ET AL.

Before the Board of Appeals

SPRUNG, HORN, KRAMER & WOODS
FOR APPELLANT

89-2572

Examiner's Answer

This is in response to appellant's brief on appeal filed 12-2-88.

(1) Status of claims .

The statement of the status of claims contained in the brief is correct.

(2) Status of Amendments After Final .

No amendment after final has been filed.

(3) Summary of invention .

The summary of invention contained in the brief is correct.

(4) Issues .

The appellant's statement of the issues in the brief is correct.

(5) Grouping of Claims .

The rejection of claims 1-7 and 11 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together. See 37 CFR 1.192(c)(5).

(6) Claims appealed .

The copy of the appealed claims contained in the Appendix to the brief is correct.

(7) Prior Art of record .

The following is a listing of the prior art of record relied upon in the rejection of claims under appeal.

(9) Grounds of rejection .

The following ground(s) of rejection are applicable to the appealed claims.

Claims 1-7 and 11 stand rejected under 35 USC 112, first paragraph, at the disclosure it enabling only for claims limited to the in vitro treatment of retro virus infected cells with 3'-deoxythymidin-2'-ene.

The claims are directed to treating warm blooded animals including humans, with the instant compound in the form of a medicament. The written description of the invention fails to present any examples showing the claimed treatment. The *in vitro* test conducted by applicants have not been shown to represent an art accepted prediction of *in vivo* effectiveness for anti-HIV in humans. Moreover there is no exemplary support in the disclosure for "warm blooded animals" and "human cells".

(10) New ground of rejection .

This Examiner's Answer does not contain any new ground of rejection.

(11) Response to argument .

Appellants' remarks regarding the rejection under 35 USC 112 first paragraph are not persuasive.

The specification is seen only as enabling for "*in vitro* blood cells." The arguments in regard to U.S. patent 4,710,492 regarding 5-halo-3'-azido-2', 3' -dideoxyuridine and Yarchoan et al regarding clinical trial of 2', 3' -dideoxycytidine (DDC) have been noted, however they are not convincing insofar as the above rejection relates to the claimed hosts since the nucelosides are not structurally similar for proper comparison and reasoning.

Appellants argue that nucleoside analogs of the instant type which are active in humans are active are

either in vitro is well taken. However, there is no evidence that the reverse situation is true. In this unpredictable areas appellants have not demonstrated the correlatability A specification is enabling for what is shows. At present, in vitro tests on HIV or AIDS virus has not been accepted in the art as being predicative of efficacy in treating human. In the absence of proper correlation between the instant data and utilization and usefulness in human, there lacks an unenabling disclosure for the claimed "warm blooded animals" or "human blood cells." The term "human blood cells" reads on cells in a living body.

For the above reasons, it is believed that the rejections should be sustained.

Respectifully submitted

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